| CMS Manual System | Department of Health & Human Services (DHHS) |
|--|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 1611 | Date: OCTOBER 3, 2008 |
| | Change Request 6205 |

SUBJECT: October 2008 Update to the Ambulatory Surgical Center (ASC) Payment System; Summary of Payment Policy Changes

I. SUMMARY OF CHANGES: This Recurring Update Notification describes changes to, and billing instructions for, payment policies implemented in the October 2008 ASC update. This update provides updated payment rates for selected separately payable drugs and biologicals and provides rates and descriptors for newly created Level II HCPCS codes for drugs and biologicals. This Recurring Update Notification applies to Pub. 100-04, chapter 14, section 10.2.

New / Revised Material

Effective Date: October 1, 2008

Implementation Date: October 6, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|-------|----------------------------------|
| N/A | |

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Attachment – Recurring Update Notification

Pub. 100-04 Transmittal: 1611 Date: October 3, 2008 Change Request: 6205

SUBJECT: October 2008 Update to the Ambulatory Surgical Center (ASC) Payment

System; Summary of Payment Policy Changes

Effective Date: October 1, 2008

Implementation Date: October 6, 2008

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification describes changes to, and billing instructions for, payment policies implemented in the October 2008 ASC update. This update provides updated payment rates for selected separately payable drugs and biologicals and provides rates and descriptors for newly created Level II HCPCS codes for drugs and biologicals.

Final policy under the revised ASC payment system, as set forth in CMS-1517-F, requires that ASC payment rates for covered separately payable drugs and biologicals be consistent with the payment rates under the Medicare hospital outpatient prospective payment system (OPPS). Beginning with the April update notification (Transmittal 1488, CR 5994) issued April 9, 2008, CMS has issued quarterly updates to ASC payment rates for separately paid drugs and biologicals and continues to update the lists of covered surgical procedures and covered ancillary services to include newly created HCPCS codes as appropriate. These policies are included in the 2008 ASC payment system instructions: Transmittal 1325 (CR 5680), issued August 29, 2007, and Transmittal 1415 (CR 5885), issued January 18, 2008.

B. Policy:

1. Billing for Drugs and Biologicals

ASCs are strongly encouraged to report charges for all separately payable drugs and biologicals, using the correct HCPCS codes for the items used. ASCs billing for these products must make certain that the reported units of service for the reported HCPCS codes are consistent with the quantity of the drug or biological that was used in the care of the patient. ASCs should not report HCPCS codes and separate charges for drugs and biologicals that receive packaged payment through the payment for the associated covered surgical procedure.

CMS reminds ASCs that under the ASC payment system if two or more drugs or biologicals are mixed together to facilitate administration, the correct HCPCS codes should be reported separately for each product used in the care of the patient. The mixing together of two or more products does not constitute a "new" drug as regulated by the Food and Drug Administration (FDA) under the New Drug Application (NDA) process. In these situations, ASCs are reminded that it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.

Unless otherwise specified in the long description, HCPCS descriptions refer to the non-compounded, FDA-approved final product. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the ASC should include the charge for the compounded product in the charge for the surgical procedure performed.

a. Drugs and Biologicals with Payment Based on Average Sales Price (ASP) Effective October 1, 2008

As stated in the CY 2008 OPPS/ASC final rule, payments for separately payable drugs and biologicals based on the average sales price (ASP) will be updated on a quarterly basis as later quarter ASP submissions become available. In cases where adjustments to payment rates for October 2008 are necessary based on the most recent ASP submissions, CMS will incorporate changes to the payment rates in the October 2008 release of the ASC DRUG file. The updated payment rates, effective October 1, 2008, will be included in the October 2008 update of the ASC Addendum BB, which will be posted on the CMS Web site at the end of September.

Instructions for downloading the ASC DRUG file updates are included in the business requirements section below. Contractors shall modify the necessary systems to accept all HCPCS codes and payment rate changes contained in this change request. Contractors shall make available to ASCs the list of any newly added codes and previous quarter payment rate changes as identified in this instruction.

Adjustment claims brought to the contractor's attention for payment rate changes identified in this instruction should be adjusted using the payment rates from the file in effect for the dates of service on the claim, including the latest revision release of a previous quarter ASC DRUG file, if issued by CMS, for the date that the service was provided.

b. New HCPCS Drug and Biological Codes that are Separately Payable Under the ASC Payment System as of October 1, 2008

Three new drug and biological HCPCS codes have been created that are payable for dates of service on or after October 1, 2008. The three new HCPCS codes, their long descriptors, and payment indicators are identified in Table 1 below.

Table 1- New Drugs and Biologicals Separately Payable under the ASC Payment System as of October 1, 2008.

| HCPCS | Long Descriptor | Payment Indicator |
|-------|--|-------------------|
| C9243 | Injection, bendamustine hcl, 1 mg | K2 |
| C9244 | Injection, regadenoson, 0.4 mg | K2 |
| C9359 | Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5cc | K2 |

c. Updated Payment Rates for Certain HCPCS Codes Effective January 1, 2008 through March 31, 2008

The payment rates for three HCPCS codes were incorrect in the January 2008 ASC DRUG file. The corrected payment rates are listed below and have been corrected in the revised January 2008 ASC DRUG file, effective for services furnished on January 1, 2008 through March 31, 2008.

Table 2- Updated Payment Rates for Certain HCPCS Codes Effective January 1, 2008

through March 31, 2008

| HCPCS Code | Short Descriptor | Corrected Payment Rate | Payment Indicator |
|---------------|-----------------------------|------------------------------|----------------------|
| J7324 | Orthovisc inj per dose | \$169.10 | K2 |
| J9015 | Aldesleukin/single use vial | \$757.34 | K2 |
| J9303 | Panitumumab injection | \$82.86 | K2 |

d. Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2008 through June 30, 2008

The payment rates for three HCPCS codes were incorrect in the April 2008 ASC DRUG file. The corrected payment rates are listed below and have been corrected in the revised April 2008 ASC DRUG file, effective for services furnished on April 1, 2008 through June 30, 2008.

Table 3- Updated Payment Rates for Certain HCPCS Codes Effective April 1, 2008 through June 30, 2008

| HCPCS | Short Descriptor | Corrected | Payment |
|-------|------------------------|-----------|-----------|
| Code | | Payment | Indicator |
| | | Rate | |
| J7324 | Orthovisc inj per dose | \$174.63 | K2 |
| J9303 | Panitumumab injection | \$82.83 | K2 |
| Q4096 | VWF complex, not | \$0.65 | K2 |
| | Humate-P | | |

e. Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2008 through September 30, 2008

The payment rate for one HCPCS code was incorrect in the July 2008 ASC DRUG file. The corrected payment rate is listed below and has been corrected in the July 2008 ASC DRUG file, effective for services furnished on July 1, 2008 through September 30, 2008.

Table 4- Updated Payment Rates for Certain HCPCS Codes Effective July 1, 2008 through September 30, 2008

| HCPCS Code | Short Descriptor | Corrected Payment Rate | • |
|---------------|------------------------|------------------------------|----|
| J7324 | Orthovisc inj per dose | \$175.85 | K2 |

f. Correct Reporting of Drugs and Biologicals When Used As Implantable Devices

With the exception of drugs and biologicals with pass-through status under the OPPS, ASCs are not to bill separately for drug and biological HCPCS codes when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. As under the OPPS, ASCs are provided a packaged payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using drugs and biologicals during covered surgical procedures as implantable devices, ASCs may include the charges for these items in their charge for the procedure.

g. Correct Reporting of Units for Drugs

ASCs are reminded to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in the HCPCS descriptor. For example, if the drug's HCPCS code descriptor specifies 6 mg, and 6 mg of the drug was administered to the patient, the units billed should be 1. As another example, if the drug's HCPCS code descriptor specifies 50 mg, but 200 mg of the drug was administered to the patient, the units billed should be 4. ASCs should not bill the units based on how the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, 10 units should be reported on the bill, even though only 1 vial was administered. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

2. Payment for Office-based Procedures and Covered Ancillary Radiology Services

The Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) requires that the Medicare physician fee schedule (MPFS) update originally applicable to dates of service January 1, 2008 through June 30, 2008 be extended through December 31, 2008. Consequently, ASC payments for some office-based procedures and covered ancillary radiology services, services for which payment is made at the lesser of the ASC rate or the MPFS non-facility PE RVU amount, are affected. As indicated in Joint Signature Memorandum 08410, issued July 16, 2008, retroactive to July 1, 2008 and through December 31, 2008, MPFS rates shall reflect the 0.5 percent update that was in effect for January – June 2008 and consistent with the MIPPA, carriers/Part B MACs shall use the same ASCFS file as used for January 1 through June 30, 2008, to make payments to ASCs for July 1, through December 31, 2008.

3. Payment for Brachytherapy Sources

The Medicare Improvement for Patients and Providers Act of 2008 requires CMS to pay for brachytherapy sources for the period of July 1, 2008 through December 31, 2009, at hospitals' charges adjusted to costs. As a result of the legislative amendment, there is no prospective rate under the OPPS for that period. Therefore, contrary to the payment policy, payment indicators and payment rates included in previous guidance, including Addendum BB to the November 27, 2007 OPPS/ASC final rule, for dates of service July 1, 2008 through December 31, 2009, payment for brachytherapy sources will be made at contractor-priced amounts, consistent with payment policy for the revised ASC payment system when no OPPS prospective rate is available.

The HCPCS codes for separately paid brachytherapy sources, long descriptors and payment indicators are listed in Table 5 below.

Table 5- Brachytherapy Sources Payable as of July 1, 2008

| HCPCS | | Payment |
|-------|---|-----------|
| Code | Long Descriptor | indicator |
| A9527 | Iodine I-125, sodium iodide solution, therapeutic, per millicurie | H7 |
| C1716 | Brachytherapy source, non-stranded, Gold-198, per source | H7 |
| C1717 | Brachytherapy source, non-stranded, High Dose Rate Iridium-192, per source | H7 |
| C1719 | Brachytherapy source, non-stranded, Non-High Dose Rate Iridium-192, per source | H7 |
| C2616 | Brachytherapy source, non-stranded, Yttrium-90, per source | H7 |
| C2634 | Brachytherapy source, non-stranded, High Activity, Iodine- 125, greater than 1.01 mCi (NIST), per source | H7 |
| C2635 | Brachytherapy source, non-stranded, High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source | H7 |
| C2636 | Brachytherapy linear source, non-stranded, Palladium-103, per 1MM | H7 |
| C2638 | Brachytherapy source, stranded, Iodine-125, per source | H7 |
| C2639 | Brachytherapy source, non-stranded, Iodine-125, per source | H7 |
| C2640 | Brachytherapy source, stranded, Palladium-103, per source | H7 |
| C2641 | Brachytherapy source, non-stranded, Palladium-103, per source | H7 |
| C2642 | Brachytherapy source, stranded, Cesium-131, per source | H7 |
| C2643 | Brachytherapy source, non-stranded, Cesium-131, per source | H7 |
| C2698 | Brachytherapy source, stranded, not otherwise specified, per source | H7 |
| C2699 | Brachytherapy source, non-stranded, not otherwise specified, per source | Н7 |

II. BUSINESS REQUIREMENTS TABLE

 $Use \ ``Shall" \ to \ denote \ a \ mandatory \ requirement$

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|----------|--|---|-------------|----|------------------|-------------|------------------|--------------|-------------|-------------|-------|
| | | A / B | D M E | FI | C A R | R H H | | Sys Iaint | | | OTHER |
| | | M A C | M A C | | R I E R | I | F I S S | M C S | V M S | C W F | |
| 6205.1 | Medicare contractors shall download and install the October 2008 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY08.DRUG.OCT.D.V0919 Date of retrieval will be provided in a separate email communication from | X | | | X | | | X | | | |
| 6205.2 | CMS Contractors shall assign TOS F to C9243, C9244, and C9359 for claims with DOS on or after October 1, 2008. | X | | | X | | | | | | |
| 6205.3 | Medicare contractors shall download and install a revised January 2008 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY08.DRUG.JAN.D.V0919 Confirmation and date of retrieval will be provided in a separate email communication from CMS. | X | | | X | | | X | | | |
| 6205.3.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service on or after January 1, 2008, but prior to April 1, 2008 and; 2) Were originally processed prior to the installation of the revised January 2008 ASC DRUG File. | X | | | X | | | X | | | |
| 6205.4 | Medicare contractors shall download and install a revised April 2008 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY08.DRUG.APR.D.V0919 Confirmation and date of retrieval will be provided in a separate email | X | | | X | | | X | | | |

| Number | Requirement | | spor lumr | | lity (| plac | e an | "X" | ' in e | ach | applicable |
|----------|---|-------------|--------------|---|------------------|-------------|-------------|---------------------|-------------|-------------|------------|
| | | A / B | D M E | F | C A R | R H H | N | Sha Sys Iaint | tem | rs | OTHER |
| | | M A C | M A C | | R I E R | I | F I S | M C S | V M S | C W F | |
| | communication from CMS | C | C | | K | | S | | | | |
| 6205.4.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service on or after April 1, 2008, but prior to July 1, 2008 and; | X | | | X | | | X | | | |
| | 2) Were originally processed prior to the installation of the revised April 2008 ASC DRUG File. | | | | | | | | | | |
| 6205.5 | Medicare contractors shall download and install a revised July 2008 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY08.DRUG.JUL.D.V0919 | X | | | X | | | X | | | |
| | Confirmation and date of retrieval will be provided in a separate email communication from CMS | | | | | | | | | | |
| 6205.5.1 | Medicare contractors shall adjust as appropriate claims brought to their attention that: 1) Have dates of service on or after July 1, 2008, but prior to October 1, 2008 and; 2) Were originally processed prior to | X | | | X | | | X | | | |
| | the installation of the revised July 2008 ASC DRUG File. | | | | | | | | | | |
| 6205.6 | Contractors shall use the ASCFS file used from January 1 through June 30, 2008 to make ASC payments for July 1 through December 31, 2008. | X | | | X | | | X | | | |
| 6205.7 | Contractors shall price brachytherapy sources based on acquisition cost or invoice if the HCPCS code is on the ASCFS and has contractor-priced payment indicator "H7." | X | | | X | | | X | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|--------|---|---|-------------|--------|-------------|--------|--------|--------|--------|--------|-------|
| | | A / | D M | F I | C A | R H | | | -Syste | | OTHER |
| | | В | Е | | R R | H I | F I | M C | V M | C W | |
| | | M A C | M A C | | I E R | | S S | S | S | F | |
| 6205.8 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | | | X | | | | | | |

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

| X-Ref | Recommendations or other supporting information: |
|-------------|--|
| Requirement | |
| Number | |
| | |
| | |

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): ASC Payment Policy: Chuck Braver at chuck.braver@cms.hhs.gov or 410-786-6719; Carrier/ AB MAC Claims Processing Issues: Yvette Cousar at yvette.cousar@cms.hhs.gov or 410-786-2160.

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs):

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.